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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,935	11/01/2001	Robert Eric Montgomery	P1088US11	9955
53/096 7590 06/26/2008 DISCUS DENTAL, LLC 8550 HIGUERA STREET CULVER CITY, CA 90232				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/039,935

**Applicant(s)**

MONTGOMERY, ROBERT ERIC

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56-58, 61-65, 67, 76 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-58, 61-65, 67, 76 and 78-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

This Office Action is in response to the Amendment filed February 4, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made NON-FINAL.

### *Claims*

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

1) Claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639).

Williams et al. disclose two part oral compositions wherein one part comprises peroxide or a peroxide releasing component and the second part comprises bicarbonate. The compositions are formulated into gels and pastes may be kept isolated in a separate compartment of a dispenser such as those disclosed by Schaeffer (US 4,849,213), which shows a dispenser comprising a compartment where the two components mix before being dispensed from the dispenser (Fig. 1 of Schaeffer). The mixture of the two components will provide a composition with a pH ranging from 7.0 to 9.5 (col. 4, lines 3-9). The peroxide releasing component includes an alkali metal percarbonate. The compositions may also comprise tartar control agents such as disodium pyrophosphate (col. 4, lines 47-58). Humectants include polyethylene glycol and may comprise 25 to 90% by weight and water may comprise 3 to 30% by weight.

The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer, the peroxide component is an anhydrous gel as in claim 71 and the compositions comprise 70% water as in claim 61.

Horner et al. disclose dispensers for flowable materials such as toothpastes. The dispensers comprise static mixers having baffles. The ingredients are mixed during passage through the discharge nozzle prior to discharge (col. 5, lines 8-12). The dispenser is a single piece, inexpensive disposable package for storing and dispensing flowable materials. It has at least two isolated chambers connected to a discharge nozzle so that the contents of the chambers are isolated until discharge. It is reliable, comfortable to hold and easy to use and comprises a static mixer for intermixing the contents of the cylinders prior to discharge. The dispenser also has a maintained dispensing volumetric ratio where the pistons travel is non-linear (col. 1, lines 53-67). The reference differs from the instant claims insofar as it does not disclose the types of toothpaste or its components that may be dispensed from the dispensers.

It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that is inexpensive disposable, has at least two isolated chambers connected to a discharge nozzle so that the contents of the chambers are isolated until discharge, is reliable, comfortable to hold and easy to use and comprises a static mixer for intermixing the contents of the cylinders prior to discharge, as disclosed by the secondary reference.

In regards to the amount of water in the compositions, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05, II. It would be obvious to one of ordinary skill in the art to have adjusted the amount of water to at least 70% water by weight motivated by the desire obtain a compositions with optimal efficacy.

In regards to the peroxide component being anhydrous, percarbonates react with water to form hydrogen peroxide<sup>1</sup>. Omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04, II. It would have been obvious to one of ordinary skill in the art to have removed water from the compositions when using percarbonates or made anhydrous compositions when using percarbonate motivated by the desire to inhibit the formation of hydrogen peroxide prematurely and ensuring a stabilized composition.

2) Claims 62, 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639) as applied to claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 in further view of Burke et al. (US 5,292,502).

The primary and secondary references, Williams et al. and Horner et al. are discussed above. Williams et al. disclose sodium bicarbonate should be incorporated

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into the compositions in order to bring the pH of the combined compositions from about 7.0 to about 9.5 (col. 4, lines 3-10). The references differ from the instant claims insofar as they do not disclose the pH adjusting agents are alkali metal carbonates and hydroxides.

Burke et al. discloses non-irritating dentifrices and is used a general teaching to disclose agents used to adjust pH to 4.5 to 9. These include sodium hydroxide, sodium citrate, benzoate, carbonate or bicarbonate. The reference differs from the instant claims insofar as it does not disclose a two part composition wherein one part comprises a hydrogen peroxide containing compound.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See MPEP 2144.06 II. It is also prima facie obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used sodium hydroxide or sodium carbonate in place of or in combination with sodium bicarbonate in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent.

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<sup>1</sup> Winston et al. US 4,812,308 disclose when water is introduced to sodium percarbonate is contacted with

3) Claims 56-57, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio (US 5,302,375) in view of Horner et al. (US 5,829,639).

Viscio discloses compositions comprising sodium percarbonate in a non-aqueous carrier. The composition may be formulated into two parts wherein the first part is a non-aqueous composition comprising a percarbonate and the second part is an aqueous composition comprising acetylsalicylic acid. The compositions comprise 40 to 70% water (col. 4, lines 60-63). The mixing of the two components will result in a mixture have a pH of less than 10 and generally in the range of from about 8.0 to about 9.0 (col. 3, lines 60-65). The pH of the acid comprising component may be adjusted to 5.0 to about 6.5 with components such as citric acid (col. 4, lines 1-6). The pH of the acid comprising component may be adjusted to below 7.0, preferably 5.0 to 6.5 (col. 3, line 68 to col. 4, line 1). The reference also discloses using sodium hydroxide to adjust comparative compositions comprising acid to increase the pH. Gelling agents such as Carbopol 941 (Example 5) are also used in the formulations and polyethylene glycol is included as a humectant. Other components include anti-tartar agents such as tetra sodium pyrophosphate (which is also a base<sup>2</sup>) and dialkali metal pyrophosphates, and peroxide stabilizers such as ethylenediaminetetraacetic acid, diethylene triaminepentaacetic acid, phosphonates such as DEQUEST (col. 6, lines 9-30).

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water, it rapidly releases hydrogen peroxide (col. 2, lines 48-55).

<sup>2</sup> Drucker, US 4,895,721 discloses tetra sodium pyrophosphate is a base that may be used to adjust pH (col. 3, lines 9-14).

The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer.

Horner et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the types of toothpaste or its components that may be dispensed from the dispensers.

It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that is inexpensive disposable, has at least two isolated chambers connected to a discharge nozzle so that the contents of the chambers are isolated until discharge, is reliable, comfortable to hold and easy to use and comprises a static mixer for intermixing the contents of the cylinders prior to discharge, as disclosed by the secondary reference.

In regards to claims 62, 75 and 79, it would have been obvious to use sodium hydroxide in the acid component of the compositions to ensure the compositions was at the desired pH as supported by MPEP 2144.07 (see above).

Claims 56-58, 61-65, 67-76 and 78-81 are rejected.

No claims allowed.



**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/

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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612